K072436

NOV - 1 2007

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information:

US Agent:	Henry Yang 25041, Farrier Circle, Laguna Hills, CA 92653
Official Correspondent:	Byungjur Park 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea
Sponsor:	BK MEDITECH Co., Ltd. 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea
Manufacturing Site:	BK MEDITECH Co., Ltd. 215-5 Yodang-Li, Yanggam-Myun, Hwasung-Si, Kyunggi-Do, Republic of Korea

Device Identification:

Trade Name:	MEGA Spine System
Common/Usual Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Spinal Pedicle Screw (MNI) per 21 CFR § 888.3070 Spondylolisthesis Spinal Fixation Device System (MNH) per 21 CFR § 888.3070

Substantially Equivalent Predicate Legally Marketed Devices

The subject device, MEGA Spine System is substantially equivalent in function design, composition, material and intended use to:

Global Spinal Fixation System(K001668) and OPTIMA™, Spinal System (K031585)

Device Description:

The MEGA Spine System is a top-loading multiple component, posterior spinal fixation systems which consist of pedicle screws, rods, locking bolt, and a cross(transverse) linking mechanism.

The MEGA Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The MEGA Spine System implant components

are supplied non-sterile, single use and fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to the ASTM F136. Various sizes of these implants are available. Specialized instruments are also available for the application and removal of the MEGA Spine System.

Indications for Use:

The MEGA Spine System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the MEGA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Performance Data:

Mechanical testing as listed in **APPENDIX 9** that was conducted in accordance with ASTM F1717 demonstrates equivalence to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BK Meditech Co., Ltd.
% Mr. Henry Yang
25041 Farrier Circle
Laguna Hills, CA 92653

NOV -- 1 2007

Re: K072436
Trade/Device Name: MEGA Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI
Dated: October 23, 2007
Received: October 23, 2007

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

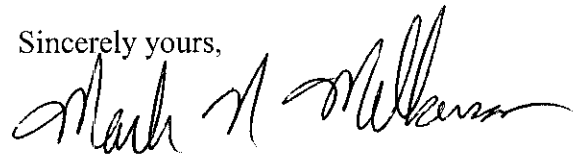
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072436

Device Name: MEGA Spinal System

Indications For Use:

The MEGA Spine System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072436